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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/786,662	02/25/2004	John D. Maynard	P0110.US2	2984
7590 08/11/2004			EXAMINER	
InLight Solutions, Inc.			KREMER, MATTHEW J	
General Counse 800 Bradbury S	= =		ART UNIT	PAPER NUMBER
Albuquerque, NM 87106			3736	
			DATE MAILED: 08/11/200	4

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)				
	10/786,662	MAYNARD ET AL.				
Office Action Summary	Examiner	Art Unit				
	Matthew J Kremer	3736				
The MAILING DATE of this communication Period for Reply	n appears on the cover sheet wit	th the correspondence address				
A SHORTENED STATUTORY PERIOD FOR RITHE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CI after SIX (6) MONTHS from the mailing date of this communication - If the period for reply specified above is less than thirty (30) days, - If NO period for reply is specified above, the maximum statutory properties of the second of the reply within the set or extended period for reply will, by any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	ON. FR 1.136(a). In no event, however, may a rein. a reply within the statutory minimum of thirty eriod will apply and will expire SIX (6) MON statute, cause the application to become AB.	eply be timely filed y (30) days will be considered timely. THS from the mailing date of this communication. ANDONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on						
	This action is non-final.					
<i>;</i> —	, -					
•	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims	,					
 4) Claim(s) 1-29 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-7,10-20 and 23-29 is/are rejected. 7) Claim(s) 8-9 and 21-22 is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement. 						
Application Papers						
9) The specification is objected to by the Exa	miner.					
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.						
Applicant may not request that any objection to						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)☐ The oath or declaration is objected to by the	ne Examiner. Note the attached	Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for for a) All b) Some * c) None of: 1. Certified copies of the priority docur 2. Certified copies of the priority docur 3. Copies of the certified copies of the application from the International Bu * See the attached detailed Office action for a	ments have been received. ments have been received in Appriority documents have been ureau (PCT Rule 17.2(a)).	pplication No received in this National Stage				
Attachment(s)	_					
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-94) Information Disclosure Statement(s) (PTO-1449 or PTO/S Paper No(s)/Mail Date 6/18/2004. 	8) Paper No(s	ummary (PTO-413))/Mail Date Iformal Patent Application (PTO-152) 				

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DETAILED ACTION

Claim Objections

Claims 6, 19, and 28 are objected to because of the following informalities.
 Claim 6 is identical to claim 5. Claim 19 is identical to claim 18. The word "on" in claim 28, line 4 should be "one". Appropriate correction is required.

Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 7 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "infrared radiation" in claims 7 and 20 is used by those claims to mean "radiation in the spectral frequency range from 4000-25000 cm⁻¹", while the accepted meaning of infrared radiation does not extend above 12500 cm⁻¹. (see Fig. 1 of U.S. Patent 6,178,346 to Amundson et al.). In other words, the Applicant is trying to expand the definition of

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infrared radiation to include the visible spectrum. The term is indefinite because the specification does not clearly redefine the term. For the purposes of examination, the term "infrared radiation" was interpreted with its accepted meaning of infrared radiation.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 5. Claims 1-7, 10-20, and 23-29 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,885,212 to Scharlack. In regard to claims 1 and 14, Scharlack teaches a method of determining blood pH by a multivariate analysis technique. (Abstract of Scharlack). Scharlack teaches that the concentration of hemoglobin is determined. (column 5, lines 18-38 of Scharlack). Scharlack teaches the use of infrared spectrum in the form of wavelengths up to 900 nm. (column 2, lines 25-33 of Scharlack). In regard to claims 2-4 and 15-17, regression coefficients are determined from calibration samples and used since classical least squares, partial least squares, or principal components regression is used. (Abstract of Scharlack). In

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regard to claims 5-6 and 18-19, transmission or reflectance measurements are used. (column 3, lines 58-64 of Scharlack). In regard to claims 7 and 20, Scharlack teaches the use of the infrared spectrum in the form of wavelengths up to 900 nm. (column 2, lines 25-33 of Scharlack). In regard to claims 11 and 24, the concentration of hemoglobin is taken from noninvasive measurement of perfused tissue. In regard to claims 12 and 25, the measurements are averaged over multiple measurements to reduce errors. (column 3, lines 42-50 of Scharlack). In regard to claims 13 and 26, the sample comprises perfused tissue. In regard to claim 14, the step of verifying that the spectrum is spectrally consistent with the calibration model is inherent in the selection of the specific wavelengths for use in the method. In regard to claims 27-28, Scharlack teaches that the device in U.S. Patent 5,355,880 to Thomas et al. (Thomas) is used. (column 2, lines 45-49 of Scharlack). Thomas teaches an illumination system that includes a broadband tungsten halogen light source 19; an illumination system and collection system that includes optical fibers 73 and 77; and an analysis system in the form of a computing unit 15. (Fig. 1 of Thomas). In regard to claim 28, it is noted that the limitations "hemoglobin concentration is determined using radiation in the spectral frequency range from 10,000 - 25,000 cm⁻¹" and " "pH is determined using radiation in the spectral frequency range from 4,000 - 10,000 cm⁻¹ combined with the hemoglobin concentration" do not add any further structural limitations to the claimed apparatus since they are method steps. In regard to claim 29, Scharlack teaches a means for determining the infrared spectrum (Fig. 1 of Thomas), a means for determining the concentration of hemoglobin (column 5, lines 18-29 of Scharlack), and a means for

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determining the pH of the sample (column 5, lines 30-44 of Scharlack). The means for selecting a model relating an infrared spectrum to pH is inherent in the system since a particular model is used, which implies that it was selected for use.

6. Claim 27 is rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication US 2003/0109772 to Mills. Mills teaches an apparatus for determining pH that includes an illumination system and collection system (Figs. 5 and 8 of Mills) and an analysis system (Fig. 11 and 14 of Mills) that comprises a model for determining sample pH from radiation expressed and a hemoglobin concentration (paragraphs 0298 and 0306 of Mills).

Allowable Subject Matter

- 7. Claims 8-9 and 21-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 8. The following is a statement of reasons for the indication of allowable subject matter. In regard to claim 8, the prior art does not teach or suggest the step of "determining an infrared spectrum comprises measuring the sample absorbance of infrared radiation in the spectral frequency range from 4000-8000 cm⁻¹" that is combined or combinable with the other limitations of claim 8. In regard to claim 9, the prior art does not teach or suggest the step of "determining an infrared spectrum comprises

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measuring the sample absorbance of infrared radiation in the spectral frequency range from 6000 – 6500 cm⁻¹" that is combined or combinable with the other limitations of claim 9. In regard to claim 21, the prior art does not teach or suggest the step of "determining an infrared spectrum comprises measuring the sample absorbance of infrared radiation in the spectral frequency range from 4000 – 8000 cm⁻¹" that is combined or combinable with the other limitations of claim 21. In regard to claim 22, the prior art does not teach or suggest the step of "determining an infrared spectrum comprises measuring the sample absorbance of infrared radiation in the spectral frequency range from 6000 - 6500 cm⁻¹" that is combined or combinable with the other limitations of claim 22.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Matthew Kremer Assistant Examiner

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